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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,295	03/12/2004	Michael P. Wallace	30-7038152001 04-050 (US0)	8148
7590	03/02/2006		EXAMINER AGUEL, FERNANDO	
Bingham McCuthen, LLP Suite 1800 Three Embarcadero San Francisco, CA 94111-4067			ART UNIT 3762	PAPER NUMBER

DATE MAILED: 03/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/799,295	Applicant(s) WALLACE ET AL.	
	Examiner Fernando Aguel	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-18, 20, 21 and 28-48 is/are pending in the application.
- 4a) Of the above claim(s) 31-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-18, 20, 21 and 28-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/12/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments, see amendment, filed 12/12/05, with respect to the underlining and bold face type of the specification have been fully considered and are persuasive. The objection of the specification has been withdrawn.
2. Applicant's arguments with respect to claims 16 and 20-24 have been considered but are moot in view of the new ground(s) of rejection.

Election/Restrictions

3. Newly submitted claims 31-48 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claims 31-34 and 45-48 are related to the elected group of claims as a combination and subcombination, and claims 35 – 44 are related to the elected group of claims as method and apparatus.
4. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 16-18, 20, 21, 28-30, drawn to a medical lead, classified in class 607, subclass 117.
 - II. Claims 31-34 and 45-48, drawn to a method, classified in class 607, subclass 116.
 - III. Claims 35-44, drawn to a medical lead, classified in class 607, subclass 116.

The inventions are distinct, each from the other because of the following reasons:

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5. Inventions II and I and III are related as process and apparatuses for its practice.

The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process.

(MPEP § 806.05(e)). In this case the apparatuses can be practiced by another and materially different process not requiring the step of compressing the medical lead.

6. Inventions III and II are related as combination and subcombination. Inventions

in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and

(2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require that the lead be configured to be expanded into a crescent cross-sectional shape, but a non-circular cross-sectional shape. The subcombination has separate utility such one not requiring a resilient spring.

7. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

8. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 31-48 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 16-18, 20 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Wilk (2001/0041821). Wilk discloses a hollow tubular membrane structure (Fig. 8, elements 70 and 60) configured to be collapsed into a compact form (paragraph 64; fig. 7c, element 12) in response to a compressive force (applied by element 54, fig. 7c) and comprises a spring element (paragraph 64, line 6; fig. 2, elements 30 and 32) or resilient mesh (paragraph 64, line 6; fig. 6, elements 44 and 46) configured to expand the lead (paragraph 64) in absence of a compressive force (paragraph 64). The lead is associated with an electrode disposed on the outer surface of the tubular structure (paragraph 63, fig. 8, element 64). The lead is inserted through the percutaneously (paragraph 60).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 16 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hess (4285347) in view of Cross et al. (2002/0111661). Hess discloses a curved, resilient, tubular epidural lead that can be straightened by a force but returns to its curved shape when the force is removed (col. 2, lines 47 – 64). Hess does not disclose that the curved shape is a crescent cross-sectional shape. Cross et al. teach an epidural lead with a crescent cross-sectional shape (fig. 3, element 14). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Hess by making the epidural lead with a crescent cross-sectional shape as taught by Cross et al. in order to insure better contact with the targeted tissue and reduce the potential for spinal cord compression (motivation suggested by Cross et al., page 3, paragraph 29).

14. In the alternative, claim 21 is rejected under 35 U.S.C. 102(b) as anticipated by Wilk (2001/0041821) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Wilk (2001/0041821) in view of Fischell et al. (4141365). Wilk discloses the invention

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substantially as claimed. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Wilk to be made to fit snugly around/in epidural space since the lead is of size and shape to fit around a heart it is of similar size to be “snugly” fit in epidural space.

15. Claims 29 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilk (2001/0041821). Wilk discloses the invention substantially as claimed but does not disclose that the tubular wall structure has a thickness in the range of 0.1mm to 2 mm, nor of 1mm or less. It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the tubular wall thickness in the range of 0.1mm to 2 mm and of 1mm or less, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

17. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fernando Aguel whose telephone number is 571-272-8687. The examiner can normally be reached on M-F, 8:30-5:00.

19. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

20. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

FA

Fernando Aguel
2/27/06

✓
GEORGE R. EVANISKO
PRIMARY EXAMINER
2/27/06